



STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements



File #
Insp #

NAME	PERMIT NUMBER	DATE OF INSPECTION	
DOING BUSINESS AS			
STREET ADDRESS		TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP	

Additional Information

Business Operation Hours

M-T-W-TH-F	Weekly Hours
Monday	Tuesday
Wednesday	Thursday
Friday	Saturday
Sunday	

Registered Pharmacist / Intern / Tech

License #	Licensee Name
License Type	
License #	Licensee Name
License Type	
License #	Licensee Name
License Type	

ACS Manager

--	--

Optional Information

--	--

Basic License Data PSD

DEA Reg #	
-----------	--

License Relations

Pharmacy Affiliate

	License #
	License #
	License #
	License #
	License #

RX DPT MGR/COR/POR

	License #
--	-----------

INV 359 - Community Requirements

Community Requirements General Section

Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]	
Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	

INV359 - Community Requirements

Insp #

File #

Prescription Department Closed sign is displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.]	
Current license of pharmacist is displayed. [465.025(7), FS] [64B16-27.100, F.A.C.]	
Consultation area available. [465.025(7), FS] [64B16-28.1035, F.A.C.]	
A sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist. [465.025(7), FS] [64B16-27.1001, F.A.C.]	
A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	
Prescription department is clean and safe, has sink/running water convenient to prescription department and adequate equipment as is necessary to the professional practice of pharmacy. [64B16-28.102, F.A.C.]	
Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.] <i>Ensure all customized medication packages are labeled with an accurate expiration date.</i>	
Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	
Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions contain information required. [893.04, F.S.]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of 456.42, F.S. [893.065, F.S.]	
Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
DEA 222 order forms properly completed. [893.07, F.S.]	
Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	
Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	
Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]	
Compounding records properly maintained. [64B16-28.140(4), F.A.C.]	
Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]	
Pedigree records are retrievable. [61N-1.012(3), F.A.C.]	
Preparation time does not exceed 1 hour when preparing, and administration begins not later than 1 hour following start of Immediate use CSPs. [64B16-27.797, F.A.C.]	
Compliant office use compounding agreement between practitioner and pharmacy available for review. [64B16-27.700 (3)(d)]	
Complete office use compounding records available for review. [64B16-27.700 (3)(e)]	
Generic equivalent sign posted [465.025(7)]	
Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1) (j), F.A.C.]	

Is there an onsite drug disposal receptacle? Or does the facility take back any drugs for destruction?

Are they an authorized collector by DEA (modifier on their DEA registration)	
Is DEA form 41 complete and maintained?	

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions	
Central Fill and originating pharmacy shall each be identified on the prescription container label.	
The word "central fill" appears on the face of the original prescription and the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal.	
The origination pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery	

Remarks:

INV359 - Community Requirements

Insp #

File #

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Investigator/Sr. Pharmacist Signature:

Representative: .

Date:

Date: